K100319

510(k) SUMMARY

GENERAL INFORMATION

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 Merit Parkway South Jordan, Utah 84095
Telephone Number:	801-208-4123 (direct)
Fax Number:	801-826-4108 (direct)
Contact Person:	Jeff Carlstrom
Date of Preparation:	February 2, 2010

APR 28 2010

DEVICE INFORMATION

Trade or Proprietary Name:	Merit Manifold with Integrated Transducer
Common or Usual Name:	Fluid Manifold; Pressure Transducer
Product Code:	DTL, DRS
Classification Name:	Disposable fluid manifold (21 CFR 870.4290) Extravascular blood pressure transducer (21 CFR 870.2850)
Classification Panel:	Cardiovascular

PREDICATE DEVICE(S)

- Merit Manifold (K913161)
- Merit Meritrans Disposable Transducer (K920977)
- Navilyst Perceptor Compensator Morse Manifold (K951722) [combined intended use]

DEVICE DESCRIPTION

The Merit Manifold with Integrated Transducer (referred to as *M-T* in this submission) is a disposable pressure transducer bonded to a 3-port manifold. The Merit *M-T* device is a sterile, precalibrated, single-use device used for both a means of interconnecting tubing, catheters, or other devices, and for physiological pressure measurement. A separate reusable interface cable is used with this system to transmit the signal from the transducer to a pressure monitor.

The *M-T* device combines two stand-alone Merit products into a single device, for ease of use and reduction of set-up time.

INTENDED USE

The Merit Manifold with Integrated Transducer is used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices. The device is also used for measurement of blood pressure.

TECHNOLOGICAL COMPARISON

Manifolds and transducers are manually operated devices that provide a user-controlled fluid pathway. The manifold body is composed of polycarbonate, with valves made of Acetal (Delrin™). The transducer package, also made of polycarbonate, is bonded to the manifold using Urethane (Meth) Acrylate blend (Dymax 20163) UV adhesive.

The technological characteristics of the Merit *M-T* device are identical to those of the Merit predicate devices in terms of intended use, clinical utility and mode of operation, user population, basic design, materials, performance, and sterilization method.

NON-CLINICAL PERFORMANCE TESTING

Verification and validation studies were conducted in accordance with in-house protocols to mitigate risks identified in the clinical risk assessment conducted by Merit. Performance testing was conducted or evaluated based on the following FDA Guidance and industry standards:

- ISO 10993-1: 2003: *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*
- FDA Bluebook memorandum G95-1: *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May, 1, 1995*
- ISO 10993-7: 1995: *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization residuals*
- ISO 11135: 1994: *Medical Devices – Validation and routine control of ethylene oxide sterilization*
- ANSI/AAMI BP 22: 1994[R]2006: *Blood Pressure Transducers*

Additional Testing not covered by these standards:

- Device Function Verification
- Transducer and Compensation Line Verification
- Bond Verification

Results of performance testing met the acceptance criteria and demonstrate substantial equivalence to the predicate devices.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Based on CDRH's substantial equivalence decision tree, the Merit Manifold with Integrated Pressure Transducer is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

APR 28 2010

Merit Medical Systems, Inc.
c/o Mr. Jeff Carlstrom
Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K100319
Trade/Device Name: Merit Manifold with Integrated Transducer
Regulatory Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcocks, manifold, or fitting
Regulatory Class: II (two)
Product Code: DTL, DRS
Dated: February 02, 2010
Received: April 23, 2010

Dear Mr. Carlstrom:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5.0

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100319

Device Name: Merit Manifold with Integrated Transducer

Indications for Use:

The Merit Manifold with Integrated Transducer is used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices. The device is also used for measurement of blood pressure.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

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